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Proposed Registration Decision PRD2016-10

Metofluthrin

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Overview

Proposed Registration Decision for Metofluthrin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of SumiOne Technical Grade, OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2 and OFF! Mosquito Coils 2, containing the technical grade active ingredient metofluthrin, as an outdoor area repellent for mosquitos.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of SumiOne Technical Grade, OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2 and OFF! Mosquito Coils 2.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on metofluthrin, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on metofluthrin, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Metofluthrin?

Metofluthrin is an active ingredient which belongs to the pyrethroid class of insecticides and is used to repel mosquitoes. OFF! Mosquito Lamp and OFF! PowerPad Mosquito Lamp 2 are domestic outdoor mosquito area repellent devices in which a candle is used to heat and release metofluthrin from an impregnated disk. OFF! Mosquito Coils 2 is an outdoor mosquito area repellent coil which is lit to release metofluthrin.

Health Considerations

Can Approved Uses of Metofluthrin Affect Human Health?

OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2 and OFF! Mosquito Coils 2, containing metofluthrin, are unlikely to affect your health when used according to label directions.

Potential exposure to metofluthrin may occur when handling and using the products. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

In laboratory animals, metofluthrin was of low acute toxicity by the oral and dermal routes of exposure. It was of slight acute toxicity by the inhalation route of exposure and as such the signal word and hazard statement "CAUTION - POISON" are required on the label. Metofluthrin was minimally irritating to the eye, was non-irritating to the skin, and did not cause an allergic skin

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

reaction. Metofluthrin does, however, belong to a class of pesticides (pyrethroids) that may cause a transient itching, tingling or burning sensation of the skin following skin contact.

OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2, and OFF! Mosquito Coils 2 products were considered of low acute toxicity by the oral and dermal routes of exposure and of slight acute toxicity by the inhalation route of exposure. They were minimally irritating to the eye, non-irritating to the skin, and did not cause an allergic skin reaction.

Registrant-supplied short, and long term (lifetime) animal toxicity tests, as well as information from the published scientific literature were assessed for the potential of metofluthrin to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment included neurotoxicity characterized by clinical signs. In addition, there was also evidence of effects on the liver. Longer-term dosing with metofluthrin resulted in liver tumors in rats, but not in mice. The risk assessment protects against the effects noted above by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

Risks in Residential Environments

Estimated risk for residential exposure is not of concern provided that use directions specified on the label are followed.

A risk assessment conducted for adults, youth and children participating in various outdoor activities while they are in the vicinity of the OFF! Mosquito Lamp, OFF! Powerpad Mosquito Lamp 2 and OFF! Mosquito Coils 2 insect repellent products indicated that risks are not of concern when these products are used according to label directions.

Environmental Considerations

What Happens When Metofluthrin Is Introduced Into the Environment?

Metofluthrin is not expected to pose an unacceptable risk to the environment when used according to product label instructions.

Metofluthrin enters the environment when used as a residential, back-yard area insect repellent that is vaporized into air through heating or burning in the proposed end-use products OFF! Mosquito Lamp, OFF! Powerpad Mosquito Lamp 2, and OFF! Mosquito Coils 2. Significant deposition of metofluthrin in the environment is unlikely due to the volatile nature of the compound, rapid transformation processes in soil, and limited exposure to the air, soil or water through this type of use. Exposure to non-target organisms is unlikely.

Value Considerations

What Is the Value of OFF! Mosquito Lamp, OFF! Powerpad Mosquito Lamp 2, and OFF! Mosquito Coils 2?

OFF! Mosquito Lamp, OFF! Powerpad Mosquito Lamp 2, and OFF! Mosquito Coils 2 can reduce the number of mosquitoes by >85% in the treated area while the products are in use.

Mosquito bites can cause discomfort and irritation, and can vector diseases such as West Nile Virus. In addition to health risks associated with mosquitos, annoyance from mosquitoes can reduce the enjoyment of being outdoors and cause people to avoid outdoor activities when mosquito populations are heavy.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

Key Risk-Reduction Measures

Human Health

The key risk-reduction measures being proposed on the labels of OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2 and OFF! Mosquito Coils 2 to address the potential risks identified in this assessment are as follows:

As the product labels state to keep out of reach of children, it is considered unlikely that children will replace the diffuser, pad or coil. To ensure that the label clearly states that refilling activity is only to be performed by adults, the following statement will be added to the product labels "only adults are permitted to replace the diffuser, pad or coil."

Next Steps

Before making a final registration decision on metofluthrin, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on metofluthrin (based on the Science Evaluation of this consultation document). In addition, the

test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Metofluthrin

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Please refer to Evaluation Report ERC2015-01, *Metofluthrin* for information on the identity of the active ingredient and the physical and chemical properties of the active ingredient.

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product – SumiOne Technical Grade

Please refer to ERC2015-01.

End-Use Products – Off! Mosquito Lamp, Off! PowerPad Mosquito Lamp 2 and Off! Mosquito Coils 2

Property	Off! Mosquito Lamp	Off! PowerPad Mosquito Lamp 2	Off! Mosquito Coils 2
Colour	Clear transparent	Blue	Tan to brown
Odour	Odourless	Slight odour	Faint (slightly alcohol-like) odour
Physical state	Solid	Solid	Solid
Formulation type	Slow-release generator	Impregnated fabric	Slow-release generator
Guarantee	Metofluthrin 9.10%	Metofluthrin 4.4%	Metofluthrin 0.02%
Container material and description	The substrate containing the active is contained in a diffuser which is placed inside the outer holder. A fresh candle is inserted at the same time as the refill. Each diffuser contains 77.8 mg ± 5 % of the a.i. Refill size range is 0.7 g to 1.5 g.	Foil pouch (plastic) 1 to 2 g is 7 cm × 2.7 cm (67 mm × 27 mm), with a resulting surface area of 12.59 cm² (1259 mm²).	The proposed product is a mosquito coil with an optional water-resistant/moisture-resistant coating. The lid of the waterproof tin will also serve as one of the holding trays. The metal tin will be packaged in a blister pack with a backer card. A separate refill package is also to be sold which contains only coils. The applicant also proposed an alternative set up which will be more cost effective containing a coil sold with a simple metal stand.

Property	OFF! Mosquito Lamp	OFF! Powerful Mosquito Lamp 2	OFF! Mosquito Coils 2
Density	1.21 g/mL at 20°C	0.4116 g/mL 20°C	0.3751 g/mL 20°C
pH at 5% dispersion in water	N/A	5.30 (5% aqueous dilution)	6.52 (5% aqueous dilution)
Oxidizing or reducing action	Does not contain any oxidizing or reducing agent.	Does not contain any oxidizing or reducing agent.	The product is not compatible with potassium permanganate which is a strong oxidizing agent.
Storage stability	Stable when stored for 2 weeks at 54°C in sealed pouch.	Stable when stored for 2 weeks at 54°C in sealed pouch.	Stable when stored for 18 days between 0° and 50°C in the original packaging.
Corrosion characteristics	No signs of corrosion or any other adverse package/product interaction were observed when stored for two weeks at 54°C	No signs of corrosion or any other adverse package/product interaction were observed when stored for two weeks at 54°C	Not corrosive to the contained material
Explosibility	Not considered to be potentially explosive.	Not considered to be potentially explosive.	Not considered to be potentially explosive.

2.3 Directions for Use

OFF! Mosquito Lamp is an outdoor mosquito area repellent device in which a dosed repellent diffuser is inserted into a lamp type device, a candle is used to heat the repellent disk releasing the impregnated active ingredient metofluthrin. OFF! Mosquito Lamp repels mosquitoes for up to 6 hours from an area of 5.05m × 5.05m.

OFF! Powerful Mosquito Lamp 2 is an outdoor mosquito area repellent device in which a dosed repellent disk is inserted into a lamp type device, a candle is used to heat the repellent disk releasing the impregnated active ingredient metofluthrin. OFF! Mosquito Lamp repels mosquitoes for up to 8 hours from an area of 5m × 5m.

OFF! Mosquito Coils 2 is an outdoor mosquito area repellent coil, the coil is lit, and as it burns it releases the active ingredient metofluthrin. OFF! Mosquito Coils 2 repels mosquitoes for up to 8 hours from an area of 4.5m × 4.5m.

2.4 Mode of Action

OFF! Mosquito Lamp, OFF! Powerful Mosquito Lamp 2, and OFF! Mosquito Coils 2 vaporise and emit metofluthrin, a pyrethroid insect repellent into the surrounding air. While mosquitoes are repelled from the treated area, the specific mode of action by which metofluthrin vapours repel mosquitoes is not certain.

2.5 Methods of Analysis

2.5 Methods for Analysis of the Active Ingredient

Please refer to EMC2015-03.

2.2 Method for Formulation Analysis

The methods provided for the analysis of the active ingredient in the formulations have been validated and assessed to be acceptable for use as enforcement analytical methods.

2.3 Methods for Residue Analysis

Please refer to EIRC 2015-01.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for metofluthrin was conducted previously and is summarized in EIRC 2015-01. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. Overall, the studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to metofluthrin.

Results of the toxicology studies conducted on laboratory animals with metofluthrin, as well as the toxicology endpoints for use in human health risk assessment, and an overall summary of the data can be found in EIRC 2015-01.

The end-use product OFF! Mosquito Lamp consists primarily of metofluthrin and, therefore, the acute toxicity profile of technical grade metofluthrin was considered representative of this product. OFF! Mosquito Lamp was considered of low acute toxicity via the oral and dermal routes, and of slight acute toxicity via the inhalation route. It was also considered minimally irritating to the eyes, non-irritating to the skin, and not a dermal sensitizer. In acute toxicity testing, the end-use products OFF! Powerpad Mosquito Lamp 2 and OFF! Mosquito Coils 2 were found to be of low acute toxicity in rats via the oral and dermal routes of exposure. They were non-irritating to the skin of rabbits, and were not skin sensitizers when tested via the Buehler method in guinea pigs. Both end-use products were considered to be slightly toxic via the inhalation route based on the results of the acute inhalation toxicity study with technical grade metofluthrin. This study was considered representative, as metofluthrin is the most toxic and volatile component of these products. The eye irritation study requirement was waived for both products, due to their physical nature (large and non-friable pad/coil). Results of the toxicology studies conducted on laboratory animals with these end-use products can be found in Appendix II, Table 1.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effect to health and the environment, to the PMRA within a set time frame. In addition, the general public, medical community, government and non-governmental organizations are able to report pesticide incidents directly to the PMRA.

As of 17 July 2015, 15 human and 1 domestic animal incident report involving metofluthrin have been submitted to the PMRA. All reported incidents were associated with the product OFF! Clip On Mosquito Repellant (Registration Number 30211). The incidents reports were considered relevant to the three proposed products given the potential for similar exposure scenarios.

Of the 15 human cases, the symptoms reported in four moderate and nine minor cases were determined to have some degree of association with the reported exposure. Two of the minor cases involved children between six and 12 years of age. Exposure to metofluthrin in most cases occurred during use of the insect repellant product as per label directions. The commonly reported route of exposure was inhalation. In five cases, other exposure scenarios were noted which included deliberate inhalation of product vapor, dermal contact with the product, and wearing the product on shirts or blouses. A wide range of symptoms were reported. These included dizziness, muscle tremors, muscle weakness, fainting, vomiting, nausea, erythema, skin irritation, swelling, irregular heart rate, lethargy, respiratory irritation and eye irritation.

The domestic animal incident occurred in Canada and involved a dog. The dog had no known direct exposure to the product containing metofluthrin; however, it was reported to have been in the general vicinity of the owner who was wearing the product. The animal experienced vocalization, fecal and urinary incontinence and a seizure.

The incidents involving metofluthrin were considered in this review and did not impact the current assessment.

3.2 Cumulative Assessment

The *Pest Control Products Act* requires the Agency to consider the cumulative effects of pest control products that have a common mechanism of toxicity. Metofluthrin belongs to a group of chemicals classified as pyrethroids. Pyrethroids and pyrethrins have a common mechanism of toxicity wherein they all possess the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. Upon completion of the re-evaluation of the individual chemicals in the pyrethroid group, it will be determined whether a cumulative effects assessment is necessary and if so, this will be performed with all relevant chemicals of the common mechanism group.

3.3 Residential Risk Assessment

3.3.1 Toxicological Endpoints

Residential exposure to OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2 or OFF! Mosquito Coils 2 insect repellents is considered short-term in duration and is predominantly by the inhalation route.

3.3.2 Residential Exposure and Risk

3.3.2.1 Residential Handler Exposure and Risk Assessment

The 2012 United States Environmental Protection Agency (USEPA) Residential Standard Operating Procedure (SOP) for candles, coils, torches and mats (CCTM) under outdoor

fogging/misting systems considers handler exposure, both dermal and inhalation, to be negligible as the application activity (in other words, product activation) does not involve application (for example, spraying liquids or spreading granules) in the typical sense.

3.3.2.2 Postapplication Residential Exposure and Risk

Potential inhalation exposure to people participating in various outdoor activities while they are in the vicinity of OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2 or OFF! Mosquito Coils 2 is expected. The exposure duration is considered short-term as described by the USEPA residential SOP for CCTM scenarios.

3.3.2.2.1 Postapplication Inhalation Exposure and Non-Cancer Risk Assessment

Inhalation exposure to residues, resulting from airborne emission, released by the proposed products when in use, is expected to adults, youths and children, since the label does not prohibit children from being in the vicinity of these products.

Postapplication exposures to these domestic products were assessed using the 2012 USEPA Residential SOP Section on, fogging and misting systems / CCTM. This section provides standard methods for estimating the potential exposure to pesticides from the use of candles, coils, torches or mats for the purposes of outdoor pest control. The SOP considers that the postapplication inhalation exposure resulting from being in proximity to CCTM products following activation to be the primary exposure route.

The SOP uses the well-mixed box (WMB) model to develop the exposure equation for the CCTM postapplication inhalation scenario. The WMB model is used to model pesticide air concentrations within an enclosed, fixed volume (in other words, a box) over time during the constant emission of a pesticide from a CCTM product. Therefore, using the WMB model is a conservative approach for estimation of exposures for an open patio or deck where dissipation is expected to be greater than the enclosed space that the WMB depicts.

The OFF! Mosquito Lamp's label, which contains the highest rate of active ingredient among the proposed products, states to use one product per 9.3m^2 (3.05m × 3.05m) and to use two or more in larger areas. Since the smallest typical area identified in the USEPA Residential SOP is larger (21.2m^2; 4.6m × 4.6m) than the label recommended area, two devices will be considered in this risk assessment.

Airflow is defined as the volume of natural air that uniformly passes through a given area in a specified period of time. The airflow used in this risk assessment is considered to be conservative as it is derived from the air velocity of calm air conditions (0.1 m/s) passing through a cross-sectional area of the space treated (11m^2) (USEPA Residential SOP, 2012).

Table 3.3.2.2.1 Inhalation Exposure Risk Estimates

Life Stage	Emission rate[1] (mg a.i./hour)	IR[2] (m^3/hour)	Airflow Q[3] (m^3/hour)	V_E[4]	Exposure Time[5] (hours/day)	Volume of Treated space[6] (m^3)	Exposure[7] (mg/kg/day)	Inhalation MOE
Adult >16	45.5	0.64	3960	1	2.3	51	0.00021023	83000
Youth 11<16 yrs	45.5	0.63	3960	1	1.9	51	2.40E-04	73000
Children 1<2 years	45.5	0.33	3960	1	2.3	51	0.000788364	22000

[1]ER = emission rate (mg a.i./hour; amount of mg a.i. in products (136.5) × number of products used (2) / useful life of product (6h))

[2]IR = Inhalation rate (m^3/hour; L)

[3]Q = airflow (m^3/hour; air velocity (0.1 m/s) × conversion factors (m/h) × cross-section of outdoor space treated ($11m^2$)).

[4]V_E = vaporization efficiency (since no data is submitted it is considered 100%)

[5]ET = exposure time (hour/day; Exposure factors handbook, 2011 using the arithmetic mean)

[6]V= volume of treated space ($51m^3$; Represent a typical treated space, USEPA Residential SOP, 2012), since this product is used for less area, this assessment considered two products to be used in 51 m^3.

[7]E = exposure (mg/kg bw/day)

$$E = [((IR.V_E.ER/Q) \times (ET - v/Q)) \times AF]/ BW$$

AF= inhalation absorption factor (100%)

BW= Body weight (kg)

[8]$$MOE = \frac{\text{Inhalation NOAEL}}{\text{Exposure}}$$

The inhalation exposure to different life stages (adults, youths and children 1<2 years) resulted in MOEs higher than the target MOE of 300. Therefore, no risk of concern is expected from the postapplication inhalation exposure to adults, youths and children when exposed to the proposed products.

3.3.2.2.2 Postapplication Inhalation Cancer Risk Assessment

To estimate the cancer risk, the average daily dose (ADD) from the inhalation exposure was calculated, after which the lifetime average daily dose (LADD) was determined. Exposure frequency was considered 15 days per year while the exposure duration was expected to be 63 years for adults, 5 years for youths and 5 years for children and a life expectancy of 78 years. The LADD was multiplied by the Q* value to determine the lifetime cancer risk (LCR).

Table 3.3.2.2.2 Inhalation Cancer Risk

Life Stage	Exposure[1] (mg/kg/day)	Exposure Frequency[2] (days/year)	Years of Exposure	Lifetime Average Daily Dose[3] (mg/kg/day)	Cancer Risk[4]
Adult >16	2.10E-04	15	63	6.98E-06	7.8853E-08
Youth 11<16 yrs	2.40E-04	15	5	6.31E-07	7.134E-09
Children 1<2 years	7.88E-04	15	5	2.08E-06	2.347E-08
Lifetime Cancer risk					1.095E-07

[1] Refer to exposure in Table 3.3.2.2.1

[2] The exposure duration is expected to be through summer months where mosquitos are prevalent (May – August). Typical seasonal use of a personal insect repellent product is estimated to be approximately 15 times over a 4 month period (May-August). Therefore, duration is considered short-term.

[3] $LADD = \frac{ADD \text{ X } Exposure\ frequency\ (day/year) \text{ X } Exposure\ duration}{365\ days/year \text{ X } Lifetime\ Years}$

[4] $LCR = LADD \times Q^*$

Table 3.3.2.2.2 indicates that estimated inhalation cancer risk is not of concern.

3.3.2.2.3 Postapplication Dermal and Non-Dietary Ingestion Exposure Assessment.

PMRA supports the approach presented in the 2012 USEPA Residential SOP for CCTM, which specifies that these exposures are expected to be negligible. No residues deposited on patios or other surfaces are expected from using CCTM product. Due to the particle sizes released from the activation of CCTM products, particles are expected to remain airborne rather than be deposited on surfaces. Therefore, dermal and incidental oral postapplication exposures to surface residues do not need to be quantitatively assessed and are not aggregated with postapplication inhalation exposure.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Metofluthrin is not expected to persist in the terrestrial environment as it is subject to rapid aerobic soil biotransformation, with 50% dissipation time (DT_{50}) values of 2.9 to 3.4 days under laboratory conditions. Its major transformation products MFOA-D and TFPA are expected to further degrade in the soil. Hydrolysis is not an important route of transformation at environmentally relevant pH. Based on the vapour pressure (1.96 × 10-3 Pa at 25°C) and the Henry's law constant (1/H= 1.754×10^3 at 25°C), metofluthrin is expected to volatilize from moist soils or water surfaces. This is consistent with the proposed use of the products. Photodegradation half- life of metofluthrin in air was estimated to be 1.7 to 1.9 hours using modelling software, indicating that breakdown is rapid. Movement through soil and partitioning to biota in water are not expected to be significant for metofluthrin.

Data on the environmental fate and behaviour of metofluthrin are summarized in Appendix I, Table 2.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications.

Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (in other words, protection at the community, population, or individual level).

The environmental risk assessment for metofluthrin was qualitative as the proposed use patterns of the end-use products OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2, and OFF! Mosquito Coils 2 will result in limited environmental exposure. The exposure cannot be quantified using standard scenarios, as the use of the product will not result in significant deposition of the active ingredient on soil, water, or plants.

4.2.1 Risks to Terrestrial Organisms

Metofluthrin is practically non-toxic to birds and wild mammals, but is highly toxic to bees and other insects (Appendix I, Table 3). This is expected as Metofluthrin is a pyrethroid insecticide. Due to the limited use of Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2, and OFF! Mosquito Coils 2, the risk to non-target insects will, however, be negligible. The active ingredient in the release from the coil or lamps in smoke or vapour only acts as an repellent in relatively small areas before it dissipates further into the surrounding air. Therefore, any potential exposure to non-target organisms would be expected to be minimal.

4.2.2 Risks to Aquatic Organisms

Metofluthrin is very highly toxic to aquatic invertebrates and fish (Appendix I, Table 3). However, due to the limited use of Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2, and OFF! Mosquito Coils 2, the risk to non-target aquatic organisms will be negligible. Exposure to the aquatic environment would be expected to be negligible since the active ingredient enters the environment as a vapour or smoke and will dissipate rapidly in air. Deposition onto water surfaces would not be expected.

5.0 Value

5.1 Consideration of Benefits

OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2, and OFF! Mosquito Coils 2 have value as they can reduce the number of mosquitoes by >85% in the treated area while the

products are in use. Mosquito bites can cause discomfort and irritation, and can vector diseases such as West Nile Virus. In addition to health risks associated with mosquitoes, annoyance from mosquitoes can reduce the enjoyment of being outdoors and cause people to avoid outdoor activities when mosquito populations are heavy.

Alternative repellent products for use against mosquitoes include skin-applied repellents (for example, sprays, wipes, and lotions) and area repellents (for example, coils and sprays). Alternative mosquito area repellents include products formulated with the active ingredients allethrin (coils and heated lamps/lanterns), garlic oil, or garlic juice.

Due to the method by which these products repel mosquitoes (in other words, area repellent using vaporized metofluthrin), they are only designed to repel mosquitoes from the area surrounding the product and take a few minutes to provide repellency after being lit. While these products reduce the number of mosquitoes in the treated area, they do not protect the user from mosquito bites and are not a replacement for a personal insect repellent product. In addition, the repellency of vapor-emitting devices such as these is reduced if there is wind, which will blow away the mosquito-repellent vapor. Because metofluthrin is a repellent and not an insecticide, development of resistance to this product is not expected.

5.2 Acceptable Claims and Effectiveness Against Pests

OFF! Mosquito Lamp

Three field trials conducted in four distinct locations (three in Florida, one in Wisconsin) were reviewed in support of OFF! Mosquito Lamp. These studies demonstrated that OFF! Mosquito Lamp will provide >85% reduction in mosquitoes from an area up to 3.05m × 3.05m for up to 6 hours.

OFF! PowerPad Mosquito Lamp 2

Three field trials conducted in three distinct locations (two in Florida, one in Wisconsin) were reviewed in support of OFF! PowerPad Mosquito Lamp 2. These studies demonstrated that OFF! PowerPad Mosquito Lamp 2 will provide >85% reduction in mosquitoes from an area up to 4.5m × 4.5m for up to 4 hours.

OFF! Mosquito Coils 2

Two field trials conducted in two distinct locations each, for a total of four locations (two in Florida, two in Wisconsin) reviewed in support of OFF! Mosquito Coils 2. These studies demonstrated that OFF! Mosquito Coils 2 will provide >85% reduction in mosquitoes from an area up to 3m × 3m for up to 4 hours.

5.3 Non-Safety Adverse Effects

No non-safety adverse effects are expected from use of OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2, or OFF! Mosquito Coils 2

5.4 Supported Uses

For OFF! Mosquito Lamp, a claim that this product repels mosquitoes from an area of 3.05m × 3.05m for up to 6 hours is supported. For OFF! PowerPad Mosquito Lamp 2, a claim that this product repels mosquitoes from an area of 4.5m × 4.5m for up to 4 hours is supported. For OFF! Mosquito Coils 2, a claim that this product repels mosquitoes from an area of 3m × 3m for up to 4 hours is supported.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity, and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, Metofluthrin and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Metofluthrin does not meet all Track 1 criteria, and is not considered a Track 1 substance. See Appendix I, Table 4 for comparison with Track 1 criteria.
- Metofluthrin does not form any transformation products that meet all Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including DIR99-03 and DIR2006-02[8], and taking into consideration the Ozone-

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5 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the New *Pest Control Products Act*.

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

- Technical grade Metofluthrin and the end-use products Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2, and OFF! Mosquito Coils 2 do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for metofluthrin is adequate to define the majority of toxic effects that may result from exposure. In acute and chronic studies conducted with laboratory animals, the primary effect of metofluthrin was neurotoxicity characterized by clinical signs. There was also evidence of hepatotoxicity. Although there was no evidence of increased susceptibility of the young in the guideline toxicity studies submitted, residual uncertainty remains concerning this matter since literature studies indicate that young animals have pharmacodynamic and pharmacokinetic differences (such as the age-dependent maturation of key metabolic processes) that may lead to increased susceptibility of the young to pyrethroid toxicity. Although there was no evidence of carcinogenicity in mice following longer-term dosing, metofluthrin was carcinogenic in rats. The risk assessment protects against the toxic effects as noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

The non-cancer inhalation risk assessments for children, youths and adults were acceptable. The lifetime inhalation cancer risk for the general population (1.1×10^{-7}) is not a concern as it is below the Agency's level of concern. Dermal and incidental non-dietary oral ingestion exposures were not assessed as the metofluthrin particles released from the activation of CCTM products are expected to remain airborne and not to be deposited on surfaces.

In light of the above, the residential exposure from using the OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2 and OFF! Mosquito Coils 2 according to label directions is not likely to result in any human health concern.

7.2 Environmental Risk

Metofluthrin is not expected to pose an unacceptable risk to the environment when used as an area repellent for insects in the end-use products Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2, and OFF! Mosquito Coils 2.

7.3 Value

OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2, and OFF! Mosquito Coils 2 have value as they can reduce the number of mosquitoes by >85% in the treated area while the products are in use. Mosquito bites can cause discomfort and irritation, and can vector diseases such as West Nile Virus. In addition to health risks associated with mosquito, annoyance from mosquitoes can reduce the enjoyment of being outdoors and cause people to avoid outdoor activities when mosquito populations are heavy.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of SumiOne Technical Grade, OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2 and OFF! Mosquito Coils 2, containing the technical grade active ingredient metofluthrin, as an outdoor area repellent for mosquitos.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

1/H	Henry's law constant
<	less than
>	greater than
≥	greater than or equal to
ADD	average daily dose
AF	inhalation absorption factor
a.i.	active ingredient
Ads.	adsorption
BAF	bioaccumulation factor
BCF	bioconcentration factor
bw or BW	body weight
CBI	confidential business information
CCTM	candles, coils, torches and mats
cm	centimetres
cm^2	centimetre squared
d	day(s)
DACO	data requirement
DIR	Regulatory Directive
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
dw	dry weight
E	exposure
EC_{50}	effective concentration on 50% of the population
EEC	estimated environmental exposure concentration
ER	emission rate
ERC	Evaluation Report
ET	exposure time
g	gram
IR	inhalation rate
kg	kilogram
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*-octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LADD	lifetime average daily dose
LCR	lifetime cancer risk
m	metre
m^2	metres squared
mg	milligram
mL	millilitre
mm	millimetre
mm^2	millimetres squared
MAS	maximum average score

MIS	maximum irritation score
MOE	*margin of exposure*
N/A	not applicable
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOI	Notice of Intent
NZW	New *Zealand* white
Pa	Pascals
pH	potential of hydrogen
PMRA	Pest Management Regulatory Agency
Q^*	cancer potency factor
Q	airflow
s	second
SOP	Standard Operating Procedure
$t_{1/2}$	half-life
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
UAN	urea ammonium nitrate
V_E	vaporization efficiency
V	volume of treated space
WMB	well-mixed box

Appendix I Tables and Figures

Table 1 Toxicity Profile of OFF! Mosquito Lamp, OFF! PowerPad Mosquito Lamp 2 and OFF! Mosquito Coils 2 Containing Metofluthrin

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/ Animal/ PMRA #	Study Results
OFF! Mosquito Lamp	
Acute oral toxicity PMRA # 2810971 & 2810972	Bridged to TGAI Low toxicity
Acute dermal toxicity PMRA # 2810971 & 2810972	Bridged to TGAI Low toxicity
Acute inhalation toxicity PMRA # 2810971 & 2810972	Bridged to TGAI Slight toxicity
Eye irritation PMRA # 2810971 & 2810972	Bridged to TGAI Minimally irritating
Dermal irritation PMRA # 2810971 & 2810972	Bridged to TGAI Non-irritating
Dermal sensitization PMRA # 2810971 & 2810972	Bridged to TGAI Non-sensitizer

Study Type/ Animal/ PMRA #	Study Results
OFF! PowerPad Mosquito Lamp 2	
Acute oral toxicity Sprague-Dawley rats PMRA # 2810994	LD_{50} > 5000 mg/kg bw Low toxicity
Acute dermal toxicity Sprague-Dawley rats PMRA # 2810995	LD_{50} > 5000 mg/kg bw Low toxicity
Acute inhalation toxicity PMRA # 2810997	Bridged to TGAI Slight toxicity
Eye irritation PMRA # 2810996	A waiver for the eye irritation study was granted based on the physical form of the product (firm, non-friable, too large to be retained in the eye)

Dermal irritation N/ZW rabbits [PMRA #2400994]	MEAS = 0, MIS = 0.7 Non-irritating
Dermal sensitization (Buehler test) Hartley guinea pigs [PMRA #2421822]	Non-sensitizer

Study Type/ Animal [PMRA #]	Study Results
CERT Powerful Mosquito Lamp 2	
Acute oral toxicity Sprague-Dawley rats [PMRA #2400991]	LD_{50} > 5000 mg/kg bw Low toxicity
Acute dermal toxicity Sprague-Dawley rats [PMRA #2400992]	LD_{50} > 5000 mg/kg bw Low toxicity
Acute inhalation toxicity [PMRA #2400993]	Bridged to TG/40 Slight toxicity
Eye irritation [PMRA #2400995]	A waiver for the eye irritation study was granted based on the physical form of the product (firm, non-friable, too large to be returned to the eye).
Dermal irritation N/ZW rabbits [PMRA #2400994]	MEAS = 0, MIS = 0.7 Non-irritating
Dermal sensitization (Buehler test) Hartley guinea pigs [PMRA #2421822]	Non-sensitizer

Table 1 Fate and Behaviour in the Environment

Study	Test substance	Value	Remarks	Reference (YYYY-MM-DD)
Hydrolysis	TG/XII	t½ at 25°C and pH 4: 11.4 days Stable at pH 7 and 9	Is not an important route of transformation	(1997-09-30)
Phototransformation in air	TG/XII	Half-life 0.7 to 3.4 hours	Values determined through modelling using the 'Atmospheric Oxidation Program for Microsoft Windows' (AOPWIN) (version 1.9) (US EPA)	(1997-09-30) (1998-02-27) (2010-10-27)
Biotransformation in aerobic soil	TG/XII	Fluorine DT_{50}: 2.9 - 5.6 d Transformation products MRP/A: DT_{50}: 0.5 to 0.8 d TFP/A: DT_{50}: 4.3 to 5.6 d	Is an important route of transformation of the parent compound	(1997-09-30) (1998-02-27) (1998-02-27)
Adsorption / desorption in soil	TG/XII	Koc: $K_{F,oc}$: 2734 - 10809	Slightly mobile to immobile	(1998-02-27)
Bioaccumulation	TG/XII	BCF: 0.09-0.09	Does not bioaccumulate significantly	(1997-10-07)

Table 2 Toxicity to Non-Target Organisms

Organism	Study type	Test substance	Endpoint value	Degree of toxicity	Reference (YYYY-MM-DD)
Terrestrial Organisms					
Rat (*Oryctolagus cuniculus*)	Acute Contact (Oral)	TG/XII	LD_{50} > 0.000 µg a.s./ Rat	Slightly toxic	(1998-02-27)
Honeybee (*Apis mellifera*)	Acute	TG/XII	LD_{50} > 0.050 µg a.s./ Kg Bee NOEL (sub-lethal effects) = 100 µg a.s./ Kg Bee	Practically non-toxic	(1998-02-27)
	Larvae (7-d)	TG/XII	LC_{50} > 5164 mg a.s./ kg diet diet NOEC (mortality & sub-lethal effects) = 5164 mg a.s./ kg diet diet	Practically non-toxic	(1998-02-27)
Mallard duck (*Anas platyrhynchos*)	Larvae (7-d)	TG/XII	LC_{50} > 5164 mg a.s./ kg diet diet NOEC (sub-lethal effects) = 1164 mg a.s./ kg diet diet	Practically non-toxic	(1998-02-27)
Rat	Acute (oral) inhalation, non-aqu.)	TG/XII	LC_{50} > 90.0-20.00 mg a.s./ m³ air equivalent to 0.90.0- 1.000 mg a.s./ L air	Moderately toxic	(1998-02-27)

Aquatic Organisms					
Invertebrate (*Daphnia magna*)	Acute (48-h)	TGAI	EC_{50} = 4.7 µg a.i./L NOEC (sub-lethal effects) = 3.0 µg a.i./L	Very highly toxic	1504810
Rainbow trout (*Oncorhynchus mykiss*)	Acute (96-h)	TGAI	LC_{50} = 1.2 µg a.i./L NOEC (mortality & sub-lethal effects) = 0.71 µg a.i./L	Very highly toxic	1504811
Bluegill sunfish (*Lepomis macrochirus*)	Acute (96-h)	TGAI	LC_{50} = 2.7 µg a.i./L NOEC (sub-lethal effects) = 1.3 µg a.i./L	Very highly toxic	1630830
Carp (*Cyprinus carpio*)	Acute (96-h)	TGAI	LC_{50} = 3.06 µg a.i./L NOEC (mortality & sub-lethal effects) = 0.712 µg a.i./L	Very highly toxic	1504812

Table 4 Toxic Substances Management Policy Considerations

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Metofluthrin endpoints
Toxic or toxic equivalent as defined by the *Canadian Environmental Protection Act*[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]	Soil	Half-life ≥ 182 days	Metofluthrin DT_{50}: 2.9-3.4 days Transformation products: MFOA-D DT_{50}: 13.4-18.2 d TFPA DT_{50}: 6.2-76.9 d
	Water	Half-life ≥ 182 days	N/A
	Sediment	Half-life ≥ 365 days	N/A
	Air	Half-life ≥ 2 days or evidence of long range transport	1.7 to 1.9 hours, Values determined through modelling using the Atmospheric Oxidation Program for Microsoft Windows (APOWIN version 1.9, USEPA)
Bioaccumulation[4]	Log K_{ow} ≥ 5		4.97 (*Z*-isomer) 5.04 (*E*-isomer)
	BCF ≥ 5000		110-120
	BAF ≥ 5000		N/A

Is the chemical a TSMP Track 1 substance (all four criteria must be met)?	No, does not meet TSMP Track 1 criteria.

[1] All pesticides will be considered toxic or toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the toxicity criterion may be refined if required (in other words, all other TSMP criteria are met).

[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, *water*, sediment or *air*) then the criterion for persistence is considered to be met.

[4] Field data (for example, bioaccumulation factors [BAFs]) are preferred over laboratory data (for example, bioaccumulation factors [BCFs]), which, in turn, are preferred over chemical properties (for example, log K_{OW}).

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

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2408938	2014, Description of Starting Materials, DACO: 3.2.1 CBI
2408939	2014, Description of Starting Materials, DACO: 3.2.1 CBI
2408941	2014, Description of the Formulation Process, DACO: 3.2.2 CBI
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2408947	2014, Establishing Certified Limits, DACO: 3.3.1 CBI
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2408953	2014, Chemical and Physical Properties, DACO: 3.5 CBI
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2408955	2014, Colour, DACO: 3.5.1 CBI
2408956	2014, Physical State, DACO: 3.5.2 CBI
2408957	2014, Odour, DACO: 3.5.3 CBI
2408958	2014, Formulation Type, DACO: 3.5.4 CBI
2408959	2014, Container Material and Description, DACO: 3.5.5 CBI
2408960	2014, Density or Specific Gravity, DACO: 3.5.6 CBI
2408961	2014, pH, DACO: 3.5.7 CBI
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2409914 2014, Chemical and Physical Properties, DACO: 3.5 CBI
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2410541 2014, Physical State, DACO: 3.5.2 CBI
2410542 2014, Odour, DACO: 3.5.3 CBI
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3.0 Environment

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B. Additional Information Considered

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